Biotech Daily

Tuesday March 17, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PHARMAXIS UP 24%, SIRTEX DOWN 55%**

*** SIRTEX TUMBLES 62% ON SIRFLOX CANCER TRIAL FAIL**

*** NHMRC $25m GRANT FOR GENOMICS RESEARCH**

*** OSPREY REQUESTS CAPITAL RAISING TRADING HALT**

*** PHARMAUST COMPLETES LOW-DOSE COHORT**

*** ACTINOGEN APPOINTS PROFS RITCHIE, MASTERS, CUMMINGS ADVISORS**

*** PRO MEDICUS COMPLETES BUY-BACK, TO BUY-BACK FURTHER 10%**

MARKET REPORT

The Australian stock market climbed 0.77 percent on Tuesday March 17, 2015 with the S&P ASX 200 up 44.4 points to 5,842.1 points.

Nine of the Biotech Daily Top 40 stocks were up, 15 fell, 14 traded unchanged and two were untraded. All three Big Caps were up.

Pharmaxis was the best, up three cents or 24 percent to 15.5 cents with 13.9 million shares traded, followed by Uscom up 10.0 percent to 22 cents with 20,000 shares traded.

Ellex climbed 4.8 percent; GI Dynamics was up 3.85 percent; Clinuvel and Tissue Therapies rose more than two percent; Alchemia, Antisense, CSL, Resmed and Medical Developments were up more than one percent; with Cochlear up 0.2 percent.

Sirtex led the falls, down as much as 62.05 percent to $14.80, before closing down $21.47 or 55.05 percent to $17.53 with 7.7 million shares traded, followed by yesterday's best, Oncosil, retreating 27.5 percent to 8.7 cents with 28.3 million shares traded.

Patrys lost 9.1 percent; Viralytics fell 8.3 percent; IDT was down 7.7 percent; Prana lost 6.7 percent; Circadian was down 5.7 percent; Genetic Technologies and Phosphagenics fell more than four percent; Acrux, Benitec and Universal Biosensors shed more than three percent; Psivida was down 1.8 percent; with Impedimed and Nanosonics down by less than one percent.

SIRTEX MEDICAL

Sirtex fell as much as 62.05 percent on news that SIR-Spheres with chemotherapy “does not result in a statistically significant improvement in the overall progression-free survival”.

Sirtex said that the 500-patient trial compared its SIR-Spheres with the current standard-of-care, oxaliplatin, leucovorin and 5- fluorouracil (Folfox) - to standard-of-care alone for non-resectable metastatic colorectal cancer.

The company said the primary endpoint was progression-free survival, with secondary endpoints including overall survival, tumor response rate, quality of life and surgical resection rate.

Sirtex said that while the Sirflox study did not show a statistically significant improvement in overall progression-free survival, it did show “a statistically significant improvement in progression-free survival in the liver”.

The company said that the preliminary analysis showed that adding SIR-Spheres Yttrium-90 resin microspheres to a current first-line systemic chemotherapy regimen for the treatment of non-resectable metastatic colorectal cancer did not result in a statistically significant improvement in the overall progression-free survival, which measured progression of existing tumors and/or the development of new tumors in any organ or body site.

Sirtex said that it was “pleased that the preliminary analysis showed that SIR-Spheres Y-90 resin microspheres did result in a statistically significant improvement in progression-free survival in the liver”.

The company said that the secondary study endpoint was important as liver tumors were commonly the only, or dominant, site of disease in patients with metastatic colorectal cancer and were the major site of disease influencing survival.

Sirtex said that up to 90 percent of metastatic colorectal cancer patients died of liver failure due to the local effects of the liver tumors.

The company said that its SIR-Spheres Y-90 resin microspheres were specifically targeted to treat liver tumors.

Sirtex said that the Sirflox study results and preliminary analysis required verification and validation through the process of academic peer review and the presentation at a scientific conference and/or publication in a medical journal were essential parts of this process.

The company said that the final results and related detailed analysis of the Sirflox study would be submitted to the American Society of Clinical Oncology meeting, to be held in Chicago, Illinois from May 29 to June 2, 2015.

In January, Sirtex said it had completed recruitment of more than 360 patients in its Foxfire Global trial of SIR-Spheres with standard-of-care for first-line metastatic colorectal cancer (BD: Jan 18, 2015).

Sirtex said at that time that the three trials Sirflox, Foxfire and Foxfire Global had recruited more than 1,000 patients with the primary endpoint of overall survival from the combined studies expected to be available by July, 2017.

Earlier this month, Sirtex said it had completed enrolment in its more than 400-patient French phase III Sarah trial directly comparing SIR-Spheres against sorafenib for liver cancer with results expected “in late 2016” (BD: Mar 5, 2015).

Last month, Sirtex said that revenue for the six months to December 31, 2014 was up 37.3 percent to $80,452,000, with dose sales up 26.3 percent to 4,950 units for the six months (BD: Feb 18, 2015).

At that time Sirtex chief medical officer Dr David Cade said that if the Sirflox trial was positive, SIR-Spheres could be used as a first line therapy.

Sirtex fell as much as $24.20 or 62.05 percent to $14.80, before closing down $21.47 or 55.05 percent at $17.53 with 7.7 million shares traded.

THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

The National Health and Medical Research Council will grant one team up to $25 million over five years for research into genomics.

The NHMRC said that the grant would be “one of the largest grants in the Council’s history” and described the opening of the grant application process “a targeted call for research into preparing Australia for the genomics revolution in health care”.

The Council said that Genomics was the study of genes, their functions and how the way they interact influences growth, development, and health throughout life and was increasingly recognized as one of the most valuable emerging tools for understanding disease.

The NHMRC said the grant would fund a research project that explored the role genomic medicine would play in improving prevention, diagnosis and treatment of disease.

The Council said that the research was expected to result in findings that would help health professionals apply genomics to the management of diseases such as cancer or diabetes.

The Council said that the research should improve our understanding of how genomic data would impact patient care and identify the economic and policy impacts of incorporating genomic data into health system activities.

The NHMRC said that the successful team would be multi-disciplinary and nationally focused, drawing on the expertise of Australia’s best researchers in this field.

NHMRC chief executive officer Prof Warwick Anderson said that genomic medicine was “truly the next frontier in how we will approach the prevention, diagnosis and treatment of disease”.

“In health care today, we can already see how genomics is making a difference in the diagnosis of some diseases, including certain types of cancers,” Prof Anderson said.

“The research conducted through this targeted call for research will yield new knowledge that will help us to understand how best to use the power of genomics to improve patient treatment,” Prof Anderson said.

“Genomic medicine has the potential to revolutionize health care, but to meet that aspiration, our understanding of the field needs to be built on the sort of rigorous research this [targeted call for research] will fund,” Prof Anderson said.

Prof Anderson said that preparing Australia for the use of genomics in health care was identified as a major health issue for the NHMRC in its 2012-’15 strategic plan.

Prof Anderson said that separately from the $25 million grant, the Council was working with practitioners, policy makers and the community to help Australia deal with the health and ethical implications of these new technologies “and ensure that we can make the most of what genomics has to offer health and medicine”.

The NHMRC said that it released resources for health professionals and consumers on direct-to-consumer genetic DNA testing, last year, which was available from its website.

The NHMRC said it was collaborating internationally through the Global Alliance for Genomics and Health and the Global Genomic Medicine Collaboration.

The Council said that the targeted call for research on genomics would close on May 13, 2015 with more information available at the NHMRC website.

OSPREY

Osprey has requested a trading halt “pending an announcement by Osprey in relation to a proposed capital raising”.

Trading will resume on March 19, 2015 or on an earlier announcement.

Osprey last traded at 58 cents.

PHARMAUST

Pharmaust says the third and final patient in the lowest dose cohort in its trial of PPL-1 for cancer at the Royal Adelaide Hospital has completed treatment.
Pharmaust said that the patient had lung cancer with metastases to the liver, brain and bone and received PPL-1 for 28 days and requested to continue into the extension phase.
The company said that subject to the recommendations of the trial safety committee and approval by the Royal Adelaide Hospital ethics committee, the trial would move onto higher doses of PPL-1.
Pharmaust said that the next dose of the drug to be tested was five times higher than the low dose cohort which received 5.0mg/kg/day.
The company said that in parallel to monitoring safety in patients who completed the full 28-day trial period, it had been monitoring pharmaco-dynamic tumor markers such as P70S6K levels in all patients who have received PPL-1 and managed to stay on therapy for at least three days.
Pharmaust said that PPL-1 was an approved veterinary drug used to treat parasitic diseases in sheep.
The company is also conducting a study of PPL-1 in dogs with cancer (BD: Dec 1, 2014)
Pharmaust was up 0.1 cents or 11.1 percent to one cent with 11.7 million shares traded.

ACTINOGEN MEDICAL

Actinogen says it has appointed Alzheimer's disease specialists Prof Craig Ritchie, Prof Colin Masters and Prof Jeff Cummings to its Xanamem advisory board.
Actinogen said that the first priority for the board would be to assist in designing the optimum phase II study to best demonstrate the efficacy and safety of Xanamem in patients with mild cognitive impairment and Alzheimer's disease, expected to begin in Australia, New Zealand, Europe and the US, under a US Food and Drug Administration approved investigational new drug application in early 2016.
The company said that Prof Ritchie would chair the advisory board.
Actinogen said that Prof Ritchie was the professor of psychiatry of ageing at the University of Edinburgh and had been the senior investigator on more than 30 drug trials of both disease-modifying and symptomatic agents for the condition.
The company said that Prof Ritchie was leading the Scottish Prevent project to identify mid-life risks for dementia and the European Prevention of Alzheimer's Dementia consortium to better understand early aspects of Alzheimer's disease before dementia developed.
The company said that Prof Masters was the executive director of Victoria's Mental Health Research Institute, a professor at the University of Melbourne and the Florey Institute of Neuroscience and Mental Health's senior deputy director, as well as a consultant at the Royal Melbourne Hospital.
Actinogen said that Prof Masters was involved with the Australian imaging, biomarkers and lifestyle (AIBL) study to determine which biomarkers, cognitive characteristics, and health and lifestyle factors determined subsequent development of Alzheimer's disease.
The company said that Prof Cummings was a professor at the Neurological Institute of Cleveland, Ohio-based Cleveland Clinic and a professor of medicine in neurology at the Case Western Reserve University.
Actinogen said that Prof Cummings was a past president of the Behavioural Neurology Society and of the American Neuropsychiatric Association and had authored or edited 39 books and published more than 650 peer-reviewed papers.
Actinogen fell 0.1 cents or 1.2 percent to 8.3 cents with 4.2 million shares traded.

PRO MEDICUS

Pro Medicus says it has completed a 12-month on-market share buy-back and will begin a new buy-back of up to 10 percent of the shares on issue beginning on April 1, 2015.
Pro Medicus said it had 100,263,406 shares on issue.
Pro Medicus was up three cents or 2.2 percent to $1.38.